

## K2 Total Conventional Hip Investigation

Note: This analysis compares the K2 femoral stem prosthesis with all other total conventional hip prostheses.

This prosthesis has been identified as having a significantly higher rate of revision. For a detailed explanation of the process used by the Registry that results in identification of prostheses that have a higher than anticipated rate of revision please refer to the Prostheses with Higher than Anticipated Rates of Revision chapter of the most recent AOANJRR Annual Report, <https://aoanjrr.sahmri.com/annual-reports-2023>.

Note: Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator. Procedures using prostheses with no recorded use in 2022 are excluded from the comparator.

### TABLE 1

#### Revision Rate of Primary Total Conventional Hip Replacement

The revision rate of the K2 total conventional hip prosthesis is compared to all other total conventional hip prostheses.

**Table 1: Revision Rates of Primary Total Conventional Hip Replacement**

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
K2	88	601	6163	1.43 (1.15, 1.76)
Other Total Conventional Hip	17452	494145	3081462	0.57 (0.56, 0.57)
<b>TOTAL</b>	<b>17540</b>	<b>494746</b>	<b>3087626</b>	<b>0.57 (0.56, 0.58)</b>

Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 2

## Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the K2 total conventional hip prosthesis is compared to all other total conventional hip prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
K2	5.2 (3.7, 7.3)	7.2 (5.4, 9.6)	7.5 (5.7, 10.0)	9.0 (6.9, 11.6)	9.8 (7.7, 12.6)	10.4 (8.2, 13.2)	11.9 (9.5, 14.8)	12.6 (10.2, 15.6)
Other Total Conventional Hip	1.7 (1.7, 1.8)	2.2 (2.1, 2.2)	2.5 (2.5, 2.6)	2.8 (2.7, 2.8)	3.1 (3.0, 3.1)	3.4 (3.3, 3.4)	3.6 (3.6, 3.7)	3.9 (3.9, 4.0)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
K2	13.4 (10.9, 16.5)	13.8 (11.2, 16.9)	14.4 (11.8, 17.6)	14.9 (12.2, 18.1)	15.4 (12.6, 18.8)	18.4 (14.2, 23.6)	
Other Total Conventional Hip	4.3 (4.2, 4.3)	4.6 (4.5, 4.7)	4.9 (4.8, 5.0)	5.3 (5.2, 5.4)	5.7 (5.6, 5.8)	6.1 (6.0, 6.2)	6.5 (6.4, 6.6)

CPR	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
K2							
Other Total Conventional Hip	6.9 (6.8, 7.1)	7.3 (7.1, 7.4)	7.6 (7.4, 7.8)	8.2 (8.0, 8.5)	8.5 (8.2, 8.8)	8.9 (8.5, 9.3)	9.3 (8.8, 9.8)

Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

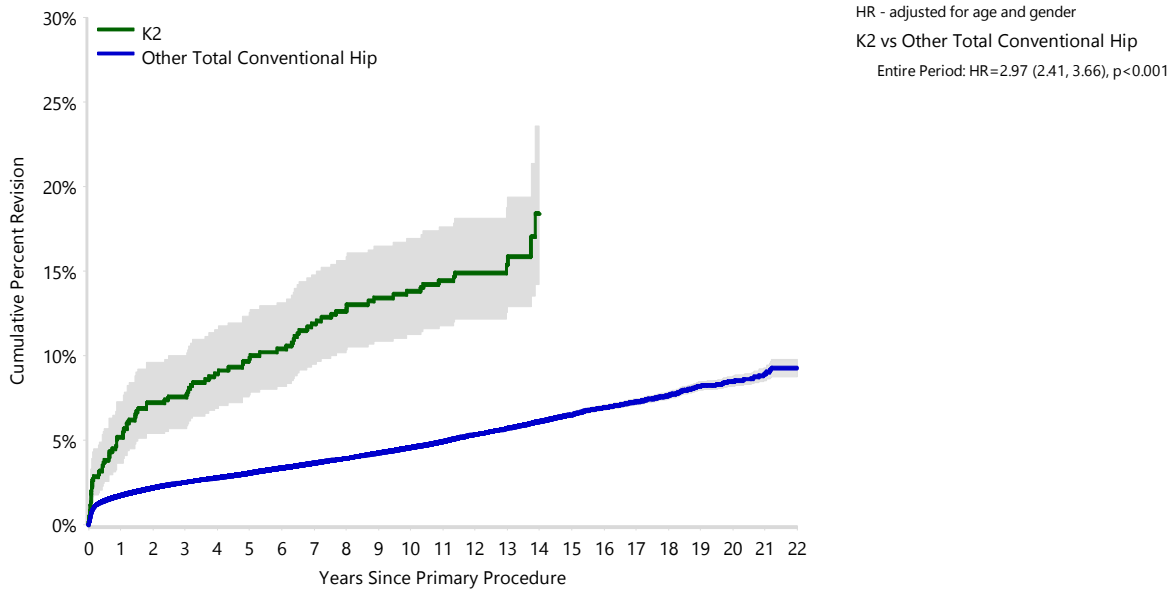
**FIGURE 1**

**Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement**

The yearly cumulative percent revision of the K2 total conventional hip prosthesis is compared to all other total conventional hip prostheses. In addition, hazard ratios are reported.

Hazard ratios are reported for specific time periods during which the hazard ratio is constant. This is done to enable more specific and valid comparisons of the risk of revision over time. The pattern of variation in risk has important implications with respect to the underlying reasons for any difference.

**Figure 1: Cumulative Percent Revision of Primary Total Conventional Hip Replacement**



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs
K2	601	564	541	533	512	500	485	470	453	437	424	408
Other Total Conventional Hip	494145	437500	388717	344220	299660	258064	219311	183514	151369	124924	102632	83483

Number at Risk	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
K2	308	173	53	15	1	0	0	0	0	0	0
Other Total Conventional Hip	66659	51987	39538	29740	22330	16535	11402	7013	3737	1435	252

Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

**TABLE 3****Primary Diagnosis for Revised Primary Total Conventional Hip Replacement**

This table identifies the diagnosis of the primary procedure which was subsequently revised. This information is provided as there is a variation on outcome depending on the primary diagnosis. It is therefore important when considering the reasons for a higher than anticipated rate of revision that there is identification of the primary diagnosis. This information should be compared to the primary diagnosis for the revisions of all other total conventional hip prostheses.

**Table 3: Primary Diagnosis for Revised Primary Total Conventional Hip Replacement**

Primary Diagnosis	K2		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	78	88.6	14432	82.7
Fractured Neck Of Femur	6	6.8	1291	7.4
Osteonecrosis	3	3.4	797	4.6
Developmental Dysplasia			279	1.6
Rheumatoid Arthritis			186	1.1
Failed Internal Fixation	1	1.1	147	0.8
Tumour			145	0.8
Other Inflammatory Arthritis			99	0.6
Fracture/Dislocation			46	0.3
Arthrodesis Takedown			16	0.1
Other			14	0.1
<b>TOTAL</b>	<b>88</b>	<b>100.0</b>	<b>17452</b>	<b>100.0</b>

Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 4

## Reasons for Revision

This is reported in two ways: a percentage of primary procedures revised and as a percentage of all revision procedures.

**% Primaries Revised:** This shows the proportional contribution of each revision diagnosis as a percentage of the total number of primary procedures. This percentage can be used to approximate the risk of being revised for that diagnosis. Differing percentages between groups, with the same distribution of follow up time, may identify problems of concern.

**% Revisions:** The number of revisions for each diagnosis is expressed as a percentage of the total number of revisions. This shows the distribution of reasons for revision within a group but cannot be used as a comparison between groups.

Table 4: Primary Total Conventional Hip Replacement - Reason for Revision (Follow-up Limited to 16.2 Years)

Revision Diagnosis	Number	K2		Other Total Conventional Hip		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	15	2.5	17.0	3994	0.8	23.1
Infection	12	2.0	13.6	3989	0.8	23.1
Fracture	11	1.8	12.5	3773	0.8	21.9
Loosening	23	3.8	26.1	3469	0.7	20.1
Pain	4	0.7	4.5	308	0.1	1.8
Leg Length Discrepancy	1	0.2	1.1	270	0.1	1.6
Malposition	1	0.2	1.1	243	0.0	1.4
Lysis	3	0.5	3.4	180	0.0	1.0
Implant Breakage Stem	2	0.3	2.3	163	0.0	0.9
Implant Breakage Acetabular Insert	2	0.3	2.3	119	0.0	0.7
Incorrect Sizing	2	0.3	2.3	102	0.0	0.6
Wear Acetabular Insert				92	0.0	0.5
Metal Related Pathology	8	1.3	9.1	71	0.0	0.4
Implant Breakage Acetabular	1	0.2	1.1	69	0.0	0.4
Wear Head				44	0.0	0.3
Tumour				40	0.0	0.2
Implant Breakage Head	1	0.2	1.1	31	0.0	0.2
Heterotopic Bone				26	0.0	0.2
Wear Acetabulum				9	0.0	0.1
Progression Of Disease				2	0.0	0.0
Osteonecrosis				1	0.0	0.0
Synovitis	1	0.2	1.1	1	0.0	0.0
Other	1	0.2	1.1	257	0.1	1.5
<b>N Revision</b>	<b>88</b>	<b>14.6</b>	<b>100.0</b>	<b>17253</b>	<b>3.5</b>	<b>100.0</b>
<b>N Primary</b>	<b>601</b>			<b>494145</b>		

Note: This table is restricted to revisions within 16.2 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

**FIGURE 2**

**Cumulative Incidence Revision Diagnosis of Primary Total Conventional Hip Replacement**

This figure details the cumulative incidence of the most common reasons for revision. The five most common reasons for revision are included as long as each of these reasons account for more than 10 procedures or at least 5% of all revisions for the K2 total conventional hip prosthesis. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total conventional hip prostheses.

**Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Conventional Hip Replacement**

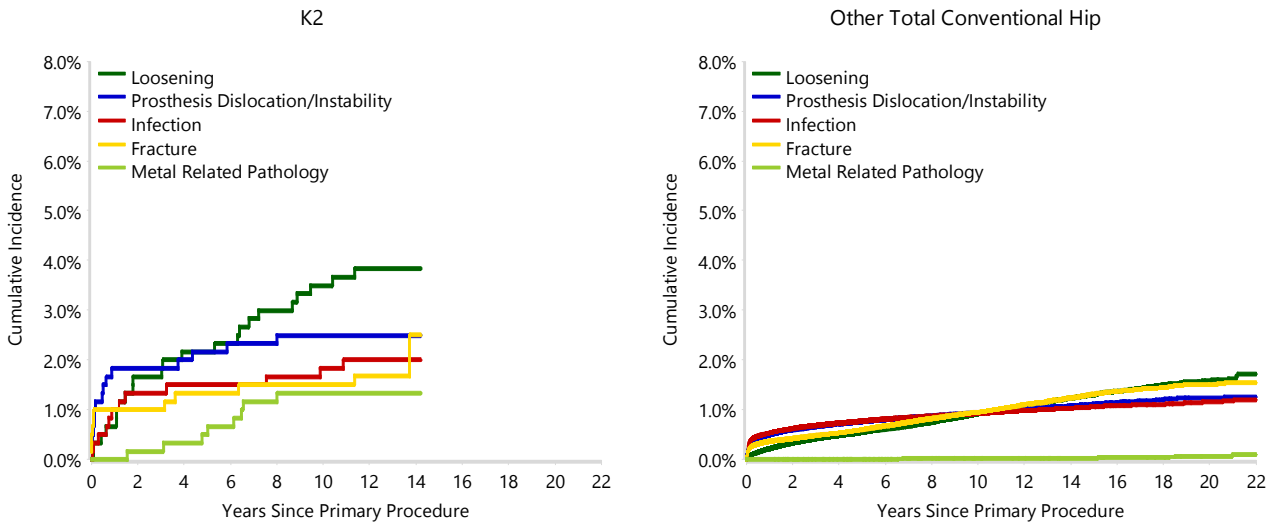


TABLE 5

### Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the K2 total conventional hip prosthesis and compares it to the components used in the revision of all other total conventional hip prostheses.

The reason this analysis is undertaken is to identify whether there is one or more components which are being replaced that differ from the components replaced for revisions of all other total conventional hip prostheses i.e. is there a difference in the type of revision undertaken for the K2 total conventional hip prosthesis compared to all other total conventional hip prostheses.

**Table 5: Primary Total Conventional Hip Replacement - Type of Revision (Follow-up Limited to 16.2 Years)**

Type of Revision	K2		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	28	31.8	5648	32.7
Acetabular Component	17	19.3	3256	18.9
THR (Femoral/Acetabular)	17	19.3	1990	11.5
Cement Spacer	6	6.8	616	3.6
Removal of Prostheses	1	1.1	94	0.5
Reinsertion of Components			27	0.2
Total Femoral			8	0.0
Bipolar Head and Femoral			5	0.0
Saddle			1	0.0
<b>N Major</b>	<b>69</b>	<b>78.4</b>	<b>11645</b>	<b>67.5</b>
Head/Insert	3	3.4	4287	24.8
Head Only	4	4.5	842	4.9
Minor Components			295	1.7
Insert Only			180	1.0
Head/Neck	8	9.1	1	0.0
Head/Neck/Insert	4	4.5		
Bipolar Only			2	0.0
Cement Only			1	0.0
<b>N Minor</b>	<b>19</b>	<b>21.6</b>	<b>5608</b>	<b>32.5</b>
<b>TOTAL</b>	<b>88</b>	<b>100.0</b>	<b>17253</b>	<b>100.0</b>

Note: This table is restricted to revisions within 16.2 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

**TABLE 6****Revision Rates of K2 Primary Total Conventional Hip Replacement by Fixation**

This analysis is provided as some prostheses have more than one fixation option. Additionally there are prostheses where an alternative to the recommended approach to fixation was used e.g. a cementless prosthesis that has been cemented or vice-versa.

**Table 6: Revised Number of K2 Primary Total Conventional Hip Replacement by Fixation**

Fixation	N Revised	N Total
Cementless	85	597
Hybrid (Femur Cemented)	0	1
Reverse Hybrid (Femur Cementless)	3	3
<b>TOTAL</b>	<b>88</b>	<b>601</b>

**TABLE 7****Revision Rates of K2 Primary Total Conventional Hip Replacement by Bearing Surface**

This analysis is provided as some prostheses are combined with a variety of bearing surfaces. All bearing surfaces used with this prosthesis are listed.

**Table 7: Revised Number of K2 Primary Total Conventional Hip Replacement by Bearing Surface**

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	56	331
Ceramic/Non XLPE	3	4
Ceramic/XLPE	9	128
Metal/Metal	17	56
Metal/Non XLPE	1	4
Metal/XLPE	2	75
Unknown	0	3
<b>TOTAL</b>	<b>88</b>	<b>601</b>

TABLE 8

**Revision Rates of Primary Total Conventional Hip Replacement by State**

This enables a state by state variation to be identified for the K2 total conventional hip prosthesis and provides the comparative data for each of the states for all other total conventional hip prostheses.

The purpose of this analysis is to determine if the higher than anticipated rate of revision has widespread distribution between states. If there is widespread distribution then the reason for the higher than anticipated rate of revision is unlikely to be surgeon specific. If the prosthesis has been used in only a small number of states it is not possible to distinguish if the higher than anticipated rate of revision is related to the prosthesis, surgeon, technique or patient.

**Table 8: Revised Number of Primary Total Conventional Hip Replacement by State**

Component	State	N Revised	N Total
K2	NSW	46	308
	VIC	37	218
	WA	4	69
	TAS	0	3
	ACT/NT	1	3
Other Total Conventional Hip	NSW	4728	144768
	VIC	4348	128324
	QLD	3451	86927
	WA	2389	58888
	SA	1621	45638
	TAS	405	16382
	ACT/NT	510	13218
<b>TOTAL</b>		<b>17540</b>	<b>494746</b>

Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

**TABLE 9****Number of Revisions of K2 Primary Total Conventional Hip Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the K2 total conventional hip prosthesis. It also provides the subsequent number of revisions of the primaries reported in that year.

Primary procedures performed in later years have had less follow up time therefore the number revised is expected to be less than the number revised in earlier years. For example, a primary procedure performed in 2022 has a maximum of one year to be revised, whereas a primary procedure performed in 2020 has a maximum of three years to be revised.

**Table 9: Number of Revisions of K2 Primary Total Conventional Hip Replacement by Year of Implant**

Year of Implant	Number Revised	Total Number
2006	0	1
2007	3	22
2008	18	80
2009	24	172
2010	35	204
2011	8	122
<b>TOTAL</b>	<b>88</b>	<b>601</b>

TABLE 10

**Revision Rates of K2 Primary Total Conventional Hip Replacement by Catalogue Number Range**

Many prostheses have a number of catalogue ranges. The catalogue range is specific to particular design features; more than one catalogue range usually indicates a minor difference in design in a particular K2 prosthesis.

This analysis has been undertaken to determine if the revision rate varies according to the catalogue number range.

Model	Catalogue Range	Catalogue Description	Cement	Material	Stem Type	Coating
<b>Femoral Stem</b>						
K2	130000-130012	POROUS TAPERED FEMORAL STEM	NO	METAL	REQUIRES FEMNECK	HA COATED
K2	130002RSA-130009RSA	FEMORAL K2 STEM RSA TITANIUM	NO	METAL	REQUIRES FEMNECK	HA COATED

**Table 10: Revised Number of K2 Primary Total Conventional Hip Replacement by Catalogue Number Range**

Femoral Stem Range	N Revised	N Total
130000-130012	84	545
130002RSA-130009RSA	4	56
<b>TOTAL</b>	<b>88</b>	<b>601</b>

**TABLE 11****Revision Rates of K2 Primary Total Conventional Hip Replacement by Component**

A prosthesis may be combined with multiple components. This analysis has been undertaken to determine if the revision rate varies according to the component with which it is combined.

**Table 11: Revised Number of K2 Primary Total Conventional Hip Replacement by Acetabular Component**

Acetabular Component	N Revised	N Total
Allofit	0	2
Bionik	1	1
Conserve Plus	0	1
Delta-TT	2	4
Fin II	44	264
Icon	17	54
Muller	1	1
PINNACLE	0	1
Procotyl L	13	130
Trabecular Metal (Shell)	0	1
Trident (Shell)	6	75
Trilogy	4	67
<b>TOTAL</b>	<b>88</b>	<b>601</b>